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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,083	09/09/2003	Simon Delagrave	bts0001-100	2730
35150	7590	03/22/2006	EXAMINER	
COZEN O' CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103			STEELE, AMBER D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/659,083	Applicant(s) DELAGRAVE, SIMON	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-50 are currently pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to a method of countering the development of resistance or neutralizing activity, classified in class 435, subclass 440+.
 - II. Claims 13-25, drawn to a method of preparing an agent, classified in class 435, subclass 4+.
 - III. Claim 26-27, drawn to a method of in vitro coevolving, classified in class 435, subclass 455+.
 - IV. Claim 28-29, drawn to a method of coevolving, classified in class 435, subclass DIG 2+.
 - V. Claim 30, drawn to a method of producing a collection of evolved targets and a collection of evolved neutralizing agents, classified in class 435, subclass DIG 46+.
 - VI. Claims 31-33, drawn to a method of treating a disease, classified in class 424, subclass 178.1+.
 - VII. Claim 34-35, drawn to a method of developing a desired characteristic in a parent antibody or parent target, classified in class 435, subclass 69.1.
 - VIII. Claim 36-37, drawn to a method of preparing an antibody, classified in class 436, subclass 547.

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- IX. Claim 38-39, drawn to an antibody, classified in class 530, subclass 387.1+.
- X. Claim 40-42, drawn to a method of treating a disease with an antibody, classified in class 424, subclass 130.1+.
- XI. Claims 43, drawn to a method of preparing an antigen, classified in class 435, subclass 69.3.
- XII. Claim 44-45, drawn to an antigen, classified in class 530, subclass 300+.
- XIII. Claim 46-50, drawn to a method of treating a disease with an antigen, classified in class 424, subclass 184.1+.

3. The inventions are distinct, each from the other because of the following reasons:

A. Inventions I-VIII, X-XI, and XIII are directed to related methods/processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups I-VIII, X-XI, and XIII have different modes of operation, function, and/or effect. For example, the invention of Group II requires the method step of “cross testing members of collections” which is not required by any of the methods of Groups I, III-VIII, X-XI, or XIII and the invention of Group V requires the method step of “selecting one or more resistant targets” which is not required by Groups I-IV, VI-VIII, X-XI, or XIII.

B. Inventions IX and XII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the

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inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design. For example, the structure of an antibody (Group IX) is different from the structure of an antigen (Group XII). The structure of an antibody is well-known in the art as a protein with specific binding and structural domains, variable regions, and constant regions while an antigen can have various structures (e.g. various 3-D conformations, various epitopes, etc.)

C. Inventions VIII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process (e.g. method of making monoclonal antibodies via hybridomas).

D. Inventions IX (product) and I-II, VII, and X (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process (e.g. method of performing flow cytometry).

E. Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process (e.g. chemical synthesis of peptides/antigens).

F. Inventions XII (product) and I-II and XIII (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process (e.g. method of making an antigen microarray).

G. Inventions IX (product) and III-VI, XI, and XIII (processes) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and/or effects.

H. Inventions XII (product) and III-VIII and X (processes) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and/or effects.

4. Because these inventions are distinct for the reasons given above and:

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- a. have acquired a separate status in the art as shown by their different classification (e.g. class and/or subclass; please refer to section 2), and/or
- b. divergent subject matter which would require different bibliographic and/or classification searches (see MPEP § 808.02); and/or
- c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

5. This application contains claims directed to the following patentably distinct species of the claimed inventions for Groups I-II, VI-VIII, X, and XIII. Election is required as follows.

6. If applicant elects the invention of Group I, the applicant is required to elect a single, specific species from **each** of the following species A-E.

A. species of what is being countered

Applicant must elect, for the purposes of search, a **single, specific species** of what is being countered.

B. species of diversifying

Applicant must elect, for the purposes of search, a **single, specific species** of diversifying.

C. species of outcome of repeating (please refer to claim 6)

Applicant must elect, for the purposes of search, a **single, specific species** of outcome of repeating.

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D. species of neutralizing agent

Applicant must elect, for the purposes of search, a **single, specific species** of neutralizing agent.

E. species of target

Applicant must elect, for the purposes of search, a **single, specific species** of target.

Claim 1 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

7. If applicant elects the invention of Group II, the applicant is required to elect a single, specific species from **each** of the following species A-D.

A. species of what is being prepared

Applicant must elect, for the purposes of search, a **single, specific species** of what is being prepared.

B. species of neutralizing agent

Applicant must elect, for the purposes of search, a **single, specific species** of neutralizing agent.

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C. species of target

Applicant must elect, for the purposes of search, a **single, specific species** of target.

D. species of coevolving

Applicant must elect, for the purposes of search, a **single, specific species** of coevolving.

Claim 13 is generic to the disclosed patentably distinct species listed above wherein the method is drawn to preparing either a neutralizing agent or a target. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

8. If applicant elects the invention of Group VI, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of disease

Applicant must elect, for the purposes of search, a **single, specific species** of disease.

Claim 31 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently

claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

9. If applicant elects the invention of Group VII, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of diversifying

Applicant must elect, for the purposes of search, a **single, specific species** of diversifying.

Claim 34 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

10. If applicant elects the invention of Group VIII, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of parent target

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Applicant must elect, for the purposes of search, a **single, specific species** of parent target.

Claim 36 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

11. If applicant elects the invention of Group X, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of disease

Applicant must elect, for the purposes of search, a **single, specific species** of disease.

Claim 40 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a

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reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

12. If applicant elects the invention of Group XIII, the applicant is required to elect a single, specific species from **each** of the following species.

A. species of disease

Applicant must elect, for the purposes of search, a **single, specific species** of disease.

Claim 46 is generic to the disclosed patentably distinct species listed above. The species are independent or distinct because the structure and/or functions are different. In addition, it would necessarily be unduly burdensome to search each of the above species of the presently claimed invention since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a **listing of all claims readable**

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Because the above restriction/election requirement is complex, a telephone call to applicant to request an oral election was not made. See MPEP § 812.01.

17. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

18. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

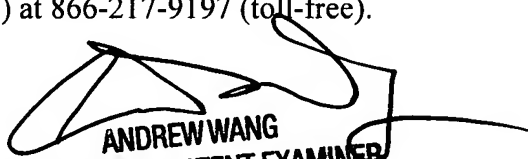
Future Communications

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS
March 6, 2006


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